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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,401

Applicant(s)

COOK, GARY P.

Examiner

S. Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 19-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S&C/2)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 04/07/09, 04/12/07.

DETAILED ACTION

Election/Restrictions

Claims 1-9 and 19-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/15/09.

Applicant's election with traverse of Group II (claims 10-18) in the reply filed on 10/15/09 is acknowledged. The traversal is on the ground(s) that there has been no showing that it would be a serious burden to search and examine the three groups together. This is not found persuasive because there is nothing of record showing that the products of Groups I and III are made by the process of Group II, given the alternative process for making the products. Similarly, there is nothing of record indicating that the product of Group I is the same as Group III. For example, Group III requires that less than about 25% of the bioactive agent is in a degraded form upon release of said bioactive agent into a physiological medium. Accordingly, for at least the above reasons, the restriction requirement is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rejected in the use of the phrase "pharmaceutical equivalents thereof" in lines 2-3. It is not entirely clear what it includes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 10-14, 16 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Orsolini et al. WO 02/058672 A2.

Orsolini teaches a sustained release microparticles formulation comprising a biodegradable polymer, a bioactive agent, a surfactant (organic ion), and an electrolyte (abstract; page 7, lines 6-15; and claims). The microparticles are prepared by providing an organic liquid phase comprising the biodegradable polymer and the bioactive agent, providing an aqueous phase comprising a surfactant, homogenizing the above organic and aqueous phases, and obtaining the microparticles (page 4, lines 17-30; page 6; and examples). Biodegradable polymer includes poly(D-L-lactide-co-glycolide) (page 8, lines 4-16). Surfactant includes anionic, non-ionic, and other surfactants (page 10, lines

8-29). Bioactive agents are disclosed in page 12, which also includes protein, peptide, polypeptide, LHRH, and the like.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orsolini et al. WO 02/058672 A2, in view of Shefer et al. WO 02/41765 A2.

Orsolini is relied upon for the reason stated above. Vuaridel does not explicitly teach the claimed organic ion.

Shefer teaches a controlled release nanoparticle comprising surfactant and co-surfactant (abstract; and claims). Co-surfactant includes cholate (page 18, lines 15 through page 19, lines 1-11). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the microparticles of Orsolini using cholate as a surfactant in view of the teachings of Shefer to obtain the claimed invention. This is because Shefer teaches the use of surfactant such as cholate in nanoparticle is well known in the art, because Shefer teaches that the present of surfactant such as phospholipid or cholate provides improved stability (ID), and because Orsolini teaches the desirability for using surfactants.

Claim 10-18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orsolini et al. WO 02/058672 A2, in view of Bodmer et al. US 5,876,761.

Orsolini is relied upon for the reasons above. Orsolini does not expressly teach the claimed bioactive agent.

Bodmer teaches a microparticles composition comprising bioactive agent such as octreotide and salt thereof. See example 4; and claim 1. The composition also comprises pamoate (column 6, lines 37-40; and column 16, lines 5-7).

Thus, it would have been obvious to one of ordinary skill in the art to modify the microparticles composition of Orsolini to include the use of octreotide as a bioactive agent, because Bodmer teaches that octreotide is a useful somatostatin, because Bodmer teaches the incorporation of octreotide in a biodegradable biocompatible polymeric carrier is known in the art (column 11, lines 42-49), and because Orsolini teaches the desirability for using somatostatin in a microparticles composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615